



UNITED STATES PATENT AND TRADEMARK OFFICE

JAN 23 2008

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

Office of Regulatory Policy  
HFD-7  
5600 Fishers Lane (Rockwall II Rm 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,583,272 was filed on December 20, 2007, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, MIRCERA® (methoxy polyethylene glycol-epoetin beta), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Because a determination has not been made whether the patent in question claims a product which has been subject to the Public Health Service Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

Mary C. Tim  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: George W. Johnston  
Hoffmann-La Roche Inc.  
Patent Law Department  
340 Kingsland Street  
Nutley, New Jersey 07110